



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0558; FRL-9387-2]

#### **Guar hydroxypropyltrimethylammonium chloride; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of guar hydroxypropyltrimethylammonium chloride (CAS Reg. No. 71329-50-5) when used as an inert ingredient (thickener/drift reduction agent) in pesticide formulations applied to growing crops. SciReg. Inc., on behalf of Rhodia Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of guar hydroxypropyltrimethylammonium chloride.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### **SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0558, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the

Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** William Cutchin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7099; email address: [cutchin.william@epa.gov](mailto:cutchin.william@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0558 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0558, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of September 28, 2012 (77 FR 59581) (FRL-9364-6), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8017) by SciReg. Inc., 12733 Director's Loop, Woodbridge, VA 22192 on behalf of Rhodia Inc. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of guar hydroxypropyltrimethylammonium chloride (CAS No. 71329-50-5) when used as an inert ingredient (thickener/drift reduction agent) in pesticide formulations applied to growing crops under 40 CFR 180.920. That notice referenced a summary of the petition prepared by Rhodia, Inc. the petitioner, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit V.C.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Nevertheless, in most instances, EPA generally exempts inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm

will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for guar hydroxypropyltrimethylammonium chloride including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with guar hydroxypropyltrimethylammonium chloride follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to

human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by guar hydroxypropyltrimethylammonium chloride as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Acute toxicity studies and mutagenicity studies were conducted with guar hydroxypropyltrimethylammonium chloride. However, guar hydroxypropyltrimethylammonium chloride has the same basic molecular structure (a high molecular weight polysaccharide backbone) as guar gum, and other slightly modified forms of guar gum. Based on common molecular structure of guar hydroxypropyltrimethylammonium chloride with guar gum, hydroxypropyl guar, carboxymethyl guar and carboxymethyl hydroxypropyl guar, it is expected that these substances would share chemical and toxicological properties.

Guar hydroxypropyltrimethylammonium chloride has a low toxicity profile. The acute oral LD<sub>50</sub> (lethal dose) is greater than 2,000 milligrams/kilogram (mg/kg). No dermal irritation, dermal sensitization, or mutagenicity was observed. Eye irritation was mild to none. Since no subchronic, reproductive and developmental, and carcinogenicity studies are available for guar hydroxypropyltrimethylammonium chloride, EPA relied on studies conducted on the structurally similar compounds guar gum, hydroxypropyl guar, and carboxymethyl guar, and carboxymethyl-hydroxypropyl guar. Subchronic, reproductive and developmental, and carcinogenicity studies with guar gum showed no long-term, reproductive/developmental toxicity or carcinogenic effects. Also

teratogenicity studies with guar gum in mice, rats, and hamsters did not indicate that guar gum is a teratogen, up to levels of 800 mg/kg/day, 900 mg/kg/day, and 600 mg/kg/day, respectively. In addition, no effects on parental fertility, fetal development, sex distribution, and no malformations of the pups were observed at doses up to 7,500 mg/kg/day in the one-generation reproduction study in rats. No evidence of immunotoxicity (spleen, thymus, blood) was observed in the available toxicity studies on structurally related chemicals. Furthermore, no clinical signs of neurotoxicity were observed at very high doses in the available database for structurally similar compounds.

Based on these data, EPA concludes that guar hydroxypropyltrimethylammonium chloride has a low toxicity profile. These findings are supported by what would be expected based on the physical characteristics of the substance. As a cationic form of guar, guar hydroxypropyltrimethylammonium chloride would be expected to be a dermal and eye irritant. Its high molecular weight as a polysaccharide polymer limits its ability to be absorbed through the skin, lungs, or gastrointestinal tract; therefore, guar hydroxypropyltrimethylammonium chloride is of low concern for acute and chronic effects, reproductive/developmental toxicity, immunotoxic, neurotoxic, and carcinogenic effects.

#### *B. Toxicological Points of Departure/Levels of Concern*

The majority of the available studies suggest that high levels of guar were well tolerated by laboratory animals. Although there were two studies that showed some effects, they appear to be outliers since those results were not replicated in the longer-term studies. In the two 90-day toxicity studies, the body weight gain appears to be depressed at 500 mg/kg/day dose levels and above. However, generally the food



consumption was not affected. In a third 90-day toxicity study in rats, no effect on body weight was observed at doses up to 3,000 mg/kg/day. No effect on the body weights were observed in the reproduction study in rats at doses up to 7,500 mg/kg/day. In the carcinogenicity studies in mice and rats by the National Toxicology Program (NTP) (1982), no adverse effects were observed at doses up to 3,570 mg/kg/day. Based on their large molecular weights, these two chemicals are not expected to be significantly absorbed via oral, dermal and inhalation routes of exposure. This is further supported by the animal toxicity studies where no significant effects were observed in a carcinogenicity studies in mice and rats and reproduction study in rats at doses up to and including 3,500 mg/kg/day. Based on the above weight of evidence, no endpoint of concern was identified; therefore, it is not appropriate to conduct a quantitative assessment.

### *C. Exposure Assessment*

#### *1. Dietary exposure from food and feed uses, drinking water, and non-dietary exposure.*

Exposure to guar hydroxypropyltrimethylammonium chloride through food, water and non-dietary sources are likely to occur. However, a quantitative exposure assessment was not conducted because no endpoint of concern (hazard) was identified in the available database.

#### *2. Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning

the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Results of toxicological studies conducted with guar hydroxypropyltrimethylammonium chloride demonstrate the substance is of low toxicity. In addition, guar hydroxypropyltrimethylammonium chloride is a slightly modified form of guar gum, a natural polymer which is an affirmed GRAS (generally recognized as safe) substance of low toxicity. Guar hydroxypropyltrimethylammonium chloride is also structurally similar to hydroxypropyl guar, carboxymethyl guar, and carboxymethyl-hydroxypropyl guar, other slightly modified forms of guar gum and all of which are exempt from the requirement of a tolerance. As part of its qualitative assessment of guar hydroxypropyltrimethylammonium chloride, EPA is not concerned about the potential for cumulative effects given the low toxicity of this substance and its structurally similar substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Guar hydroxypropyltrimethylammonium chloride is a slightly modified form of guar gum, a natural polymer which is an affirmed GRAS substance of low toxicity. Guar hydroxypropyltrimethylammonium chloride is also structurally similar to hydroxypropyl guar, another slightly modified form guar gum. According to EPA's 2005 tolerance exemption reassessment document for hydroxypropyl guar, it was concluded that

hydroxypropyl guar is a high molecular weight polymer that is devoid of reactive functional groups and which is not absorbed by any route of human exposure. Also teratogenicity studies with guar gum in mice, rats, and hamsters did not indicate that guar gum is a teratogen, up to levels of 800 mg/kg, 900 mg/kg, and 600 mg/kg, respectively. In addition, no effects on parental fertility, fetal development, sex distribution, and no malformations of the pups were observed at doses up to 7,500 mg/kg/day in the 1-generation reproduction study in rats. Based on the structural similarities to guar gum and hydroxypropyl guar, as well as its high molecular weights and low likelihood of absorption via any route of exposure, guar hydroxypropyltrimethylammonium chloride is unlikely to elicit a toxic response in infants and children when used as an inert ingredient in pesticide products. Available toxicity studies support this conclusion of low toxicity.

#### *E. Aggregate Risks and Determination of Safety*

In examining aggregate exposure, EPA considers available information concerning exposures from the pesticide residue in food and all other nonoccupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Based on results from toxicological studies, its close structural relationship to guar gum, hydroxypropyl guar, carboxymethyl guar, and carboxymethyl-hydroxypropyl guar, as well as its high molecular weight and low likelihood of absorption via any route of exposure, guar hydroxypropyltrimethylammonium chloride is considered to be a low toxicity substance. Taking into consideration all available information on guar hydroxypropyltrimethylammonium chloride, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and

children, will result from aggregate exposure to guar hydroxypropyltrimethylammonium chloride under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of guar hydroxypropyltrimethylammonium chloride when used as an inert ingredient in pesticide formulations applied, is safe under FFDCA section 408.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for guar hydroxypropyltrimethylammonium chloride.

### *C. Response to Comments*

One comment was received for a notice of filing from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for guar hydroxypropyltrimethylammonium chloride (CAS No. 71329-50-5) when used as an inert ingredient (thickener/drift reduction agent) in pesticide formulations applied to growing crops.

## **VII. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health

Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 20, 2013.

**Lois Rossi,**

*Director, Office of Pesticide Programs.*



Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.920, the table is amended by alphabetically adding the following inert ingredient to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *		* *
Guar hydroxypropyltrimethylammonium chloride (CAS Reg. No. 71329-50-5)		Thickener/drift reduction agent
* * *		* *